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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/695,886 | 10/29/2003 | Andrew B. Lederman | 050508-1110 | 7813 |
| 24504 7590 02/21/2007 THOMAS, KAYDEN, HORSTEMEYER & RISLEY, LLP 100 GALLERIA PARKWAY, NW STE 1750 ATLANTA, GA 30339-5948 | | | EXAMINER BACHMAN, LINDSEY MICHELE | |
| | | | ART UNIT 3734 | PAPER NUMBER |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/695,886

Applicant(s)

LEDERMAN, ANDREW B.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This Action is in response to Applicant's amendment filed on 30 November 2006.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. In Claim 1, Applicant states that the front and rear surfaces extend side-by-side along at least a portion of the shaft. In Claims 2-7, Applicant discloses a second front and second rear surface. These front and rear surfaces are disclosed as being proximal and distal to the tip of the needle, respectively. There is no differentiation between the front and rear surface disclosed in Claim 1 and the front and rear surface disclosed in Claims 2-7 and it is not clear what Applicant intends to claim as his invention.

Appropriate corrections are required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8, 10-14, 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brunken (EP 0 615 726 A1).

6. Claims 1 and 10: Brunken'726 discloses a needle with a curved cylindrical shaft (2, Figure 1) having a front surface and rear surface being marked at least partially with a visual indicator (page 2, lines 29-34) and a puncture tip (6) at one end of the curve (see Figure 1) of the shaft (2).

7. Claims 2-7: Brunken'726 discloses a shaft having a front surface (near tip 6) that includes a visual indicator of bare or untreated metal, which is a first color, and a rear surface, distal to the tip, that includes a visual indicator that is matte-finished or colored, which is a second color (page 2, lines 29-34).

8. Claim 8: Brunken'726 discloses that the entire front surface of the needle consists of bare or untreated metal (first color) and rear surface can be continuously matte-finished or colored (second color) (page 2, lines 29-34 and Figure 1).

9. Claim 11, 12, and 14: Brunken'726 discloses a surgical needle with a curved cylindrical shaft (Figure 1) containing a puncture tip (6) and a shaft (2) extending from the tip (6) including a means for distinguishing between the front surface of the shaft (2) that is proximal to tip (6) and the rear surface of the shaft (2) that is distal to tip (6) (see Figure 1).

10. Claim 12: Brunken'726 discloses a shaft having a front surface (near tip 6) that includes a visual indicator of bare or untreated metal, which is a first color, and a rear

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surface that includes a visual indicator that is matte-finished or colored, which is a second color (page 2, lines 29-34).

11. Claim 13: Brunken'726 discloses that the entire front surface of the needle consists of bare or untreated metal (first color) and rear surface can be continuously matte-finished or colored (second color) (page 2, lines 29-34 and Figure 1).

12. Claim 20: Brunken'726 discloses a method of making a suture needle that includes providing a suture needle (page 3, lines 5-9) and marking at least a portion of the needle with a visual indicator (page 3, lines 14-17). The portion must extend at least partially along a length of the needle.

13. Claim 21: Brunken'726 discloses that the front surface is a different color than the rear surface of the needle (page 3, lines 18-19).

14. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsutani, et al. (US Patent 4,935,029).

15. Matsutani'029 discloses a suture needle (Figure 16) that contains a shaft (7) having a front surface (I) and a rear surface (O) (see Figures 12-15) that extend side by side along at least a portion of the shaft (see band 4 in Figure 16). The portions are marked with a visual indicator (4) that can differentiate the front and rear portions of the shaft from one another (columns 10-11). The device also contains a pucture tip at its distal end (see Figure 16). Further, it would be obvious to extend these visual indicators along the entire shaft in order to aid a surgeon in recognizing the orientation of the needle at the distal tip (columns 10-11).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brunken'726, as applied to Claim 1, in view of Anis (US Patent 5,352,233).

19. Brunken'726 teaches the limitations of Claim 9, except a mechanism for determining the needle's angle of orientation.

20. Anis'233 teaches a medical device in which a visual indicator on the device aids in determining the angle of orientation of the instrument (column 3, lines 58-68) in order to aid the surgeon in orienting the device (column 3, lines 30-36). Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a visual indicator to aid in determining the angle of orientation of the device.

Response to Arguments

21. Applicant argues that Brunken'726 does not disclose a visual indicator that differentiates between the front and rear surface that extends side-by-side along the length of the needle shaft.

22. Claims 1-14: All suture needles have a front and rear surface that extend side-by-side along the length of the shaft, including the needle taught by Brunken'726. Applicant does not claim a visual indicator differentiating between the front and rear portions that extend side-by-side. Therefore, the Brunken'726 meets the limitations of the claims. Further, Matsutani'029 discloses a visual indicator on a needle that differentiates with a color between the inner and outer portions of the needle along its shaft.

23. Claims 20-21: Brunken'726 clearly indicates that different portions of the shaft are treated. For example, zone 8 is discussed on page 3, line 10-13 can be colored, while page 3, lines 18-19 discuss that the remaining portion of the needle (10) can be left untreated creating a different color. This clearly extends at least partially along the length of the suture needle.

24. Regarding Applicant's arguments of inherency in the Conclusion, it is stated in CFR 1.111 that Applicant must be specific in their arguments. Since the argument of inherency does not address any specific portions of Examiner's Office Action, it will not be addressed.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

26. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MICHAEL J. HAYES
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